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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/758,902 | 01/11/2001 | Roberts S. David | PC9047D | 1327 |

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| EXAMINER |
|---|
| DUFFY, PATRICIA ANN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/758,902 | DAVID ET AL. | |
| | Examiner | Art Unit | |
| | Patricia A. Duffy | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19, 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## RESPONSE TO AMENDMENT

The amendment filed 5-2-06 has been entered into the record. Claims 1-18 have been cancelled. Claims 19 and 20 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

### *Rejections Withdrawn*

The requirement for sequence compliance was in error and is withdrawn.

### *Rejections Maintained*

Claims 19 and 20 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,083,512 in view of Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.) and Kensil et al for reasons made of record in the Office Action mailed 11-28-05.

Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983) in view of Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) for reasons made of record in the Office Action mailed 11-28-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the Seifert reference does not present any actual data of protection for the composition. This is not persuasive; the reference does not have to present actual protection data. The statement of protection alone is sufficient. Applicants argue the document referenced by Seifert and indicate that filed experiments are insufficient to provide evidence of protection against virulent Clostridium. This is not

persuasive; Applicants admit that the field results were positive. Positive field results are positive for protection see at page 2 and were specifically characterized as "marked protective effect" as compared with animal which were not vaccinated. This statement alone indicates that there was a protective effect in a controlled experiment. Applicants also argue the observed deaths in the field experiment. This argument is not persuasive. The death rate in an experiment is not relevant to the claims because the reference admits a protective effect in animals with an appropriate control was observed. The deaths are irrelevant to the report of that observation. It is noted that applicants are arguing protection from death, however, it is noted that this limitation is not in the claims and vaccines in general have a failure rate. The fact that some were protected and acknowledged as protected by the author is sufficient. Applicants argue that the references do not teach or remotely suggest that saponins adjuvant as the sole adjuvant and that the evidence of record that anthrax spores can act as both adjuvant and antigen. This is not persuasive; the claim language is viewed as "open". The term an adjuvant "consisting essentially of a saponin" is being read as open because there is no evidence in the specification as filed that and those additional components do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). Further, the claim is not limited to a single adjuvant because the vaccine comprises. Applicants limitation to sole is an argument for consisting of language and not the consisting essentially of as currently set forth in claim 20. Applicants argue

that there is no teaching in the prior art that saponins as the sole adjuvant would be effective for clostridial vaccines. This is not persuasive; the claims are not so limited. The claim is not a vaccine "consisting of" the three ingredients but comprising. With respect to that there is not recognition in the art that saponins could be used as a sole adjuvant to enhance a multicomponent clostridial vaccine is not persuasive because if it was, it would be a 102 rejection and the claims are not so limited. Additionally, all that is required is a reasonable expectation of success and not an absolute prediction of success. It is noted that Kensil et al teaches that "... saponins have been extensively employed as adjuvants in vaccines against foot and mouth disease and in amplifying the protective immunity conferred by experimental vaccines against protozoal parasites such as *Tyrpanosoma cruzi* plasmodium and also the humoral response to sheep red blood cells (SRBC)." (column 1, lines 25-30). Thus, Kensil et al teach reasonable expectation of success as an adjuvant in vaccines given the noted extensive employment of saponins as adjuvants in vaccines. Furthermore, Kensil et al at Figures 12-15 teach that the combination of saponins with the adjuvant $Al(OH)_3$ does not affect the basic characteristic of the composition because the combination still provides for the generation of an immune response against the antigen and is effective "alone" as an adjuvant to antigens. As such, the addition of the additional component in the composition comprising the adjuvant consisting essentially of a saponins, does not materially affect the basic characteristic of the composition. That is the combination of art of record, would reasonably be expected to provide for an immunogenic vaccine composition given the known ability of the protein antigens of the prior art as protective and the known effect of saponins as adjuvants for stimulating an immune response alone or in combination with other adjuvants. Furthermore, the use of saponins alone as an adjuvant was specifically demonstrated to be effective to provide for an immune response against the antigen of interest (Figures 12 and 15). Applicants mischaracterize the teachings of Kensil and do not appreciate the full scope of the teachings of Kensil et al of

record. Applicants argue that none of the secondary references including Green et al cure the deficiencies of Seifert and Kensil. This is not persuasive; there is no deficiency in either Seifert or Kensil et al for reasons set forth supra. The references as combined provide a reasonable expectation of success.

Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983), Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil (US Patent 5,057,540 issued 1991) as applied to claim 20 above further in view of Green et al (The Veterinary Record, 120:435-439, 1987) for reasons made of record in the Office Action mailed 11-28-05.

Applicants essentially argue the same as for the combination of Seifert (Deutsche Tiearzliche Wochem. 90(7):274-279, 1983), Geresi et al (Ann. Immunol. Hung. 25(0):37-40, 1985), Farmers and Consumers Market Bulletin (Department of Agriculture, Atlanta, Georgia, 70(24): 1984, page 1, 12, ill.), and Kensil et al above and argue that the rejection fails over the further combination with Green et al because Green et al does not cure the deficiencies of the initial combination set forth for claim 20. This is not persuasive, the combination of Seifert, Geresi and Kensil et al does not fail for claim 20 as set forth directly above and therefore the rejection is maintained.

## *Status of Claims*

Claims 19 and 20 stand rejected.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645